

REMARKS

Claims 3, 5, and 8 are amended to remove multiple dependency. Claims 10-22 are new. Support for the new claims and the amendment to Claims 3, 5, and 8 can be found in the originally filed claims and throughout the specification. No new matter is believed to be introduced by the above amendment.

Claims 1-3 and 5-22 are pending. Favorable reconsideration is respectfully requested.

At the outset, Applicants thank Examiner Sheikh for the helpful suggestions in the Office Action and discussions of the present application between the date of the mailing the Office Action and the date of the presently filed documents, which are summarized and expanded upon below. Further, Applicants thank Examiner Sheikh for indicating the above amendment, combined with the following remarks appear to further favorable prosecution of the present invention.

Claims 1-3 and 5-9 are rejected under 35 U.S.C. 103(a) over Kobayashi et al.; USP 6,187,842. The rejection is traversed below.

The object of Kobayashi et al. is to obtain a gellant that easily disperses in an aqueous solution and form a gel at room temperature. Kobayashi et al. disclose, at best, a sugar compound used as a gellant in an aqueous medium. Kobayashi et al. further disclose that a cosmetic composition can be produced by gelling an aqueous medium using this gellant. Kobayashi et al. disclose the use of a surfactant to promote the dispersion of the sugar compound in an aqueous solvent using this gellant. Still further, Kobayashi et al. disclose dispersing the sugar compound and the dispersant in water to form a gel, **then lyophilizing to remove the water in the gel to obtain a xerogel powder-type gellant composition.** However, Kobayashi et al. neither disclose nor suggest a **water-containing powder** which may be obtained by coating an aqueous gel with hydrophobic particles which may be used in cosmetics, much less an aqueous gel as a core being coated with particles.

In direct contrast, the present invention relates, in part, to a **water-containing powder** composition obtained by causing water to gel with a gellant then coating the gel with hydrophobic particles. The object of the present invention, in part, is to provide a **water-containing powder** that exhibits excellent production stability and storage stability, and breaks and releases water when pressed with the fingers or the like during use. The freeze-shattering of the aqueous gel of the present invention is only given as one example for forming the aqueous gel into particles. The freeze-shattering is not conducted to remove the water from the aqueous gel.

The Examiner's attention is directed to the enclosed definition of "xerogel" as defined by the IUPAC Compendium of Chemical Terminology, 2nd Ed (1997) which states:

"Xerogel: A term used for the dried out open structures which have passed a gel state during preparation"

In light of the above definition of xerogel as accepted by IUPAC, it is clear that a "dried out" structure is in exact opposite to the present invention which relates to a water-containing powder, not a water-removed xerogel composition as described in Kobayashi et al. In fact, since the present invention contains a water-containing powder and Kobayashi et al. discloses a xerogel, it appears as if Kobayashi et al. actually teaches directly away from the claimed invention.

Kobayashi et al. clearly fails to disclose or suggest all limitations of the claimed invention as required by the MPEP (see § 2143.03 and the enclosed copy of *In re Royka* 180 USPQ 580 (CCPA 1974)). Accordingly, any combination of the above-mentioned references clearly fails to anticipate the claimed invention, much less suggest it. Additionally, it has not been pointed out to the Applicants as to where any specific motivation lies within any of the

above-mentioned references that would motivate the skilled artisan reading the same to modify the process disclosed therein towards the claimed invention.

In light of the above, it appears as if the Examiner is relying on the Applicants disclosure to supply motivation to modify the disclosure of Kobayashi et al. to arrive at the claimed invention. However, this is clearly improper according to a recent decision (enclosed) by the U.S. Federal Courts in *In re Lee* (61 USPQ2D 1430 (CA FC 2002)). The *Lee* Court indicated that the Office must provide specific motivation, hint, or suggestion, found in the references relied upon to support a prima facie case of obviousness. In the present case, the Office appears to rely on the present specification for motivation, which is clearly forbidden according to the *Lee* Court. In light of this decision, Applicants respectfully request the Office not to use the present specification as a guidepost to combine the disparate disclosures of the cited references (see the enclosed decision in *In re Vaeck* 20 USPQ 2d 1438).

In view of the above, Kobayashi et al. clearly fails to disclose, much less suggest the claimed invention. Therefore, no prima facie case of obviousness can possibly exist over Kobayashi et al. Accordingly, withdrawal of this grounds of rejection is respectfully requested.

Applicants respectfully submit that the present application is now in condition for allowance. Favorable reconsideration is respectfully requested. Should anything further be required to place this application in condition for allowance, the Examiner is requested to contact the undersigned by telephone.

Respectfully submitted,

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xerogel

A term used for the dried out open structures which have passed a *gel* stage during preparation (e.g. silica gel); and also for dried out compact macromolecular gels such as gelatin or rubber.

1972, 31, 606

In re Vaeck (CA FC) 20 USPQ2d 1438

In re Vaeck

**U.S. Court of Appeals Federal Circuit
20 USPQ2d 1438**

**Decided October 21, 1991
No. 91-1120**

Headnotes

PATENTS

1. Patentability/Validity - Obviousness - Combining references (§ 115.0905)

Rejection of claimed subject matter as obvious under 35 USC 103 in view of combination of prior art references requires consideration of whether prior art would have suggested to those of ordinary skill in art that they should make claimed composition or device, or carry out claimed process, and whether prior art would also have revealed that such person would have reasonable expectation of success; both suggestion and reasonable expectation of success must be founded in prior art, not in applicant's disclosure.

2. Patentability/Validity - Obviousness - Relevant prior art - Particular inventions (§ 115.0903.03)

Patent and Trademark Office has failed to establish prima facie obviousness of claims for use of genetic engineering techniques for producing proteins that are toxic to insects such as larvae of mosquitos and black flies, since prior art does not disclose or suggest expression in cyanobacteria of chimeric gene encoding insecticidally active protein, or convey to those of ordinary skill

reasonable expectation of success in doing so; expression of antibiotic resistance-conferring genes in cyanobacteria, without more, does not render obvious expression of unrelated genes in cyanobacteria for unrelated purposes.

3. Patentability/Validity - Specification - Enablement (§ 115.1105)

JUDICIAL PRACTICE AND PROCEDURE

Procedure - Judicial review - Standard of review - Patents (§ 410.4607.09)

Specification must, in order to be enabling as required by 35 USC 112, first paragraph, teach 'person skilled in art to make and use invention without "undue experimentation," which does not preclude some experimentation; enablement is question of law which is reviewed independently on appeal, although such determination is based upon underlying factual findings which are reviewed for clear error.

PATENTS

4. Patentability/Validity - Specification - Enablement (§ 115.1105)

Patent and Trademark Office did not err in rejecting, as non-enabling pursuant to 35 USC 112, first paragraph, claims for use of genetic engineering techniques for producing proteins that are toxic to insects such as larvae of mosquitos and black flies, in view of relatively incomplete understanding of biology of cyanobacteria as of applicants' filing date, as well as limited disclosure by applicants of particular cyanobacterial genera operative in claimed invention, since there is no reasonable correlation between narrow disclosure in applicants' specification and broad scope of protection sought in claims encompassing gene expression in any and all cyanobacteria.

Case History and Disposition:

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Application for patent, serial no. 07/021,405, filed March 4, 1987, by Mark A. Vaeck, Wipa Chungjatupornchai, and Lee McIntosh (hybrid genes incorporating a DNA fragment containing a gene coding for an insecticidal protein, plasmids, transformed cyanobacteria expressing such protein and method for use as a biocontrol agent). From decision rejecting claims 1-48 and 50-52 as unpatentable under 35 USC 103, and rejecting claims 1-48 and 50-51 for lack of enablement, applicants appeal. Affirmed and part and reversed in part; Mayer, J., dissents with opinion.

Attorneys:

Ian C. McLeod, Okemos, Mich., for appellant.

Teddy S. Gron, associate solicitor (Fred E. McKelvey, solicitor and Richard E. Schafer, associate solicitor, with him on brief), for appellee.

Judge:

Before Rich, Archer, and Mayer, circuit judges.

Opinion Text

Opinion By:

Rich, J.

This appeal is from the September 12, 1990 decision of the Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (Board), affirming the examiner's rejection of claims 1-48 and 50-52 of application Serial No. 07/021,405, filed March 4, 1987, titled "Hybrid Genes Incorporating a DNA Fragment Containing a Gene Coding for an Insecticidal Protein, Plasmids, Transformed Cyanobacteria Expressing Such Protein and Method for Use as a Biocontrol Agent" as unpatentable under 35 USC 103, as well as the rejection of claims 1-48 and 50-51 under 35 USC 112, first paragraph, for lack of enablement. We reverse the § 103 rejection. The § 112 rejection is affirmed in part and reversed in part.

BACKGROUND

A. The Invention

The claimed invention is directed to the use of genetic engineering techniques 1 for production of

proteins that are toxic to insects such as larvae of mosquitos and black flies. These swamp-dwelling pests are the source of numerous human health problems, including malaria. It is known that certain species of the naturally-occurring *Bacillus* genus of bacteria produce proteins ("endotoxins") that are toxic to these insects. Prior art methods of combatting the insects involved spreading or spraying crystalline spores of the insecticidal *Bacillus* proteins over swamps. The spores were environmentally unstable, however, and would often sink to the bottom of a swamp before being consumed, thus rendering this method prohibitively expensive. Hence the need for a lower-cost method of producing the insecticidal *Bacillus* proteins in high volume, with application in a more stable vehicle.

As described by appellants, the claimed subject matter meets this need by providing for the production of the insecticidal *Bacillus* proteins within host cyanobacteria. Although both cyanobacteria and bacteria are members of the procaryote 2 kingdom, the

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cyanobacteria (which in the past have been referred to as "blue-green algae") are unique among procaryotes in that the cyanobacteria are capable of oxygenic photosynthesis. The cyanobacteria grow on top of swamps where they are consumed by mosquitos and black flies. Thus, when *Bacillus* proteins are produced within transformed 3 cyanobacterial hosts according to the claimed invention, the presence of the insecticide in the food of the targeted insects advantageously guarantees direct uptake by the insects.

More particularly, the subject matter of the application on appeal includes a chimeric (i.e., hybrid) gene comprising (1) a gene derived from a bacterium of the *Bacillus* genus whose product is an insecticidal protein, united with (2) a DNA promoter effective for expressing 4 the *Bacillus* gene in a host cyanobacterium, so as to produce the desired insecticidal protein.

The claims on appeal are 1-48 and 50-52, all claims remaining in the application. Claim 1 reads:

1. A chimeric gene capable of being expressed in Cyanobacteria cells comprising:

(a) a DNA fragment comprising a promoter region which is effective for expression of a DNA fragment in a Cyanobacterium; and

(b) at least one DNA fragment coding for an insecticidally active protein produced by a *Bacillus* strain, or coding for an insecticidally active truncated form of the above protein or coding for a protein having substantial sequence homology to the active protein, the DNA fragments being linked so that the gene is expressed.

Claims 2-15, which depend from claim 1, recite preferred *Bacillus* species, promoters, and selectable markers. 5 Independent claim 16 and claims 17-31 which depend therefrom are directed to a hybrid plasmid vector which includes the chimeric gene of claim 1. Claim 32 recites a bacterial strain. Independent claim 33 and claims 34-48 which depend therefrom recite a cyanobacterium which expresses the chimeric gene of claim 1. Claims 50-51 recite an insecticidal composition. Claim 52 recites a particular plasmid that appellants have deposited.

B. Appellants' Disclosure

In addition to describing the claimed invention in generic terms, appellants' specification

discloses two particular species of *Bacillus* (*B. thuringiensis*, *B. sphaericus*) as sources of insecticidal protein; and nine genera of cyanobacteria (*Synechocystis*, *Anacystis*, *Synechococcus*, *Agmenellum*, *Aphanocapsa*, *Gloecapsa*, *Nostoc*, *Anabaena* and *Ffremyllia*) as useful hosts.

The working examples relevant to the claims on appeal detail the transformation of a single strain of cyanobacteria, i.e., *Synechocystis* 6803. In one example, *Synechocystis* 6803 cells are transformed with a plasmid comprising (1) a gene encoding a particular insecticidal protein ("B.t. 8") from *Bacillus thuringiensis* var. *israelensis*, linked to (2) a particular promoter, the P_L promoter from the bacteriophage Lambda (a virus of *E. coli*). In another example, a different promoter, i.e., the *Synechocystis* 6803 promoter for the rubisco operon, is utilized instead of the Lambda P_L promoter.

C. The Prior Art

A total of eleven prior art references were cited and applied, in various combinations, against the claims on appeal.

The focus of Dzelzkalns, 6 the primary reference cited against all of the rejected claims, is to determine whether chloroplast promoter sequences can function in cyanobacteria. To that end Dzelzkalns discloses the expression in cyanobacteria of a chimeric gene comprising a chloroplast promoter sequence fused to a gene encoding the enzyme chloramphenicol acetyl transferase (CAT). 7 Importantly, Dzelzkalns teaches the use of the CAT gene as a "marker" gene; this use of antibiotic resistance-conferring genes for selection purposes is a common technique in genetic engineering.

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Sekar I, 8 Sekar II, 9 and Ganesan 10 collectively disclose expression of genes encoding certain *Bacillus* insecticidal proteins in the bacterial hosts *B. megaterium*, *B. subtilis* and *E. coli*. Friedberg 11 discloses the transformation of the cyanobacterium *Anacystis nidulans* R2 by a plasmid vector comprising the O_LP_L operator-promoter region and a temperature-sensitive repressor gene of the bacteriophage Lambda. While the cyanobacteria are attractive organisms for the cloning of genes involved in photosynthesis, Friedberg states, problems may still be encountered such as suboptimal expression of the cloned gene, detrimental effects on cell growth if overexpressed, highly hydrophobic proteins, and rapid turnover of some gene products. To address these problems, Friedberg teaches the use of the disclosed Lambda regulatory signals in plasmid vehicles which, it states, have "considerable potential for use as vectors the expression of which can be controlled in *Anacystis*"

Miller 12 compares the initiation specificities *in vitro* of DNA-dependent RNA polymerases 13 purified from two different species of cyanobacteria (*Fremyella diplosiphon* and *Anacystis nidulans*), as well as from *E. coli*.

Nierzwicki-Bauer 14 identifies in the cyanobacterium *Anabaena* 7120 the start site for

transcription of the gene encoding *rbc* L, the large subunit of the enzyme ribulose-1, 5-bisphosphate carboxylase. It reports that the nucleotide sequence 14-8 base pairs preceding the transcription start site "resembles a good *Escherichia coli* promoter," but that the sequence 35 base pairs before the start site does not.

Chauvat 15 discloses host-vector systems for gene cloning in the cyanobacterium *Synechocystis* 6803, in which the antibiotic resistance-conferring *neo* gene is utilized as a selectable marker.

Reiss 16 studies expression in *E. coli* of various proteins formed by fusion of certain foreign DNA sequences with the *neo* gene.

Kolowsky 17 discloses chimeric plasmids designed for transformation of the cyanobacterium *Synechococcus* R2, comprising an antibiotic-resistant gene linked to chromosomal DNA from the *Synechococcus* cyanobacterium.

Barnes, United States Patent No. 4,695,455, is directed to the treatment with stabilizing chemical reagents of pesticides produced by expression of heterologous genes (such as those encoding *Bacillus* proteins) in host microbial cells such as *Pseudomonas* bacteria. The host cells are killed by this treatment, but the resulting pesticidal compositions exhibit prolonged toxic activity when exposed to the environment of target pests.

D. The Grounds of Rejection

1. The § 103 Rejections

Claims 1-6, 16-21, 33-38, 47-48 and 52 (which include all independent claims in the application) were rejected as unpatentable under 35 USC 103 based upon Dzelzkalns in view of Sekar I or Sekar II and Ganesan. The examiner stated that Dzelzkalns discloses a chimeric gene capable of being highly expressed in a cyanobacterium, said gene comprising a promoter region effective for expression in a cyanobacterium operably linked to a structural gene encoding CAT. The examiner acknowledged that the chimeric gene and transformed host of Dzelzkalns differ from the claimed invention in that the former's structural gene encodes CAT rather than insecticidally active protein. However, the examiner pointed out, Sekar I, Sekar II, and Ganesan teach genes encoding insecticidally active proteins produced by *Bacillus*, and the advantages of expressing such genes in heterologous hosts to obtain larger quantities of the protein. The examiner contended that it would have been obvious to one of ordinary skill in the art to substitute the *Bacillus* genes taught by Sekar I, Sekar II, and Ganesan for the CAT gene in the vectors of Dzelzkalns in order to obtain high level expression of the *Bacillus* genes in the transformed cyanobacteria. The examiner further contended that it would have been obvious to use cyanobacteria as heterologous hosts for expression of the claimed genes due to the ability of cyanobacteria to serve as transformed hosts for the

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expression of heterologous genes. In the absence of evidence to the contrary, the examiner contended, the invention as a whole was prima facie obvious.

Additional rejections were entered against various groups of dependent claims which we need

not address here. All additional rejections were made in view of Dzelzkalns in combination with Sekar I, Sekar II, and Ganesan, and further in view of other references discussed in Part C above. The Board affirmed the § 103 rejections, basically adopting the examiner's Answer as its opinion while adding a few comments. The legal conclusion of obviousness does not require absolute certainty, the Board added, but only a reasonable expectation of success, citing *In re O'Farrell*, 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988). In view of the disclosures of the prior art, the Board concluded, one of ordinary skill in the art would have been motivated by a reasonable expectation of success to make the substitution suggested by the examiner.

2. The § 112 Rejection

The examiner also rejected claims 1-48 and 50-51 under 35 USC 112, first paragraph, on the ground that the disclosure was enabling only for claims limited in accordance with the specification as filed. Citing *Manual of Patent Examining Procedure* (MPEP) provisions 706.03(n) 19 and (z) 20 as support, the examiner took the position that undue experimentation would be required of the art worker to practice the claimed invention, in view of the unpredictability in the art, the breadth of the claims, the limited number of working examples and the limited guidance provided in the specification. With respect to unpredictability, the examiner stated that

the cyanobacteria comprise a large and diverse group of photosynthetic bacteria including large numbers of species in some 150 different genera including *Synechocystis*, *Anacystis*, *Synechococcus*, *Agmenellum*, *Nostoc*, *Anabaena*, etc. The molecular biology of these organisms has only recently become the subject of intensive investigation and this work is limited to a few genera. Therefore the level of unpredictability regarding heterologous gene expression in this large, diverse and relatively poorly studied group of procaryotes is high....

The Board affirmed, noting that "the limited guidance in the specification, considered in light of the relatively high degree of unpredictability in this particular art, would not have enabled one having ordinary skill in the art to practice the broad scope of the claimed invention without undue experimentation. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970)."

OPINION

A. Obviousness

We first address whether the PTO erred in rejecting the claims on appeal as prima facie obvious within the meaning of 35 USC 103. Obviousness is a legal question which this court independently reviews, though based upon underlying factual findings which we review under the clearly erroneous standard. *In re Woodruff*, 919 F.2d 1575, 1577, 16 USPQ2d 1934, 1935 (Fed. Cir. 1990).

[1] Where claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of

ordinary skill would have a reasonable expectation of success. *See In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure. *Id.*

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[2] We agree with appellants that the PTO has not established the prima facie obviousness of the claimed subject matter. The prior art simply does not disclose or suggest the expression in cyanobacteria of a chimeric gene encoding an insecticidally active protein, or convey to those of ordinary skill a reasonable expectation of success in doing so. More particularly, there is no suggestion in Dzelzkalns, the primary reference cited against all claims, of substituting in the disclosed plasmid a structural gene encoding *Bacillus* insecticidal proteins for the CAT gene utilized for selection purposes. The expression of antibiotic resistance-conferring genes in cyanobacteria, without more, does not render obvious the expression of unrelated genes in cyanobacteria for unrelated purposes.

The PTO argues that the substitution of insecticidal *Bacillus* genes for CAT marker genes in cyanobacteria is suggested by the secondary references Sekar I, Sekar II, and Ganesan, which collectively disclose expression of genes encoding *Bacillus* insecticidal proteins in two species of host *Bacillus* bacteria (*B. megaterium* and *B. subtilis*) as well as in the bacterium *E. coli*. While these references disclose expression of *Bacillus* genes encoding insecticidal proteins in certain transformed bacterial hosts, nowhere do these references disclose or suggest expression of such genes in transformed cyanobacterial hosts.

To remedy this deficiency, the PTO emphasizes similarity between bacteria and cyanobacteria, namely, that these are both procaryotic organisms, and argues that this fact would suggest to those of ordinary skill the use of cyanobacteria as hosts for expression of the claimed chimeric genes. While it is true that bacteria and cyanobacteria are now both classified as procaryotes, that fact alone is not sufficient to motivate the art worker as the PTO contends. As the PTO concedes, cyanobacteria and bacteria are not identical; they are classified as two separate divisions of the kingdom Procaryotae. 21 Moreover, it is only in recent years that the biology of cyanobacteria has been clarified, as evidenced by references in the prior art to "blue-green algae." Such evidence of recent uncertainty regarding the biology of cyanobacteria tends to rebut, rather than support, the PTO's position that one would consider the cyanobacteria effectively interchangeable with bacteria as hosts for expression of the claimed gene.

At oral argument the PTO referred to additional secondary references, not cited against any independent claim (i.e., Friedberg, Miller, and Nierzwicki-Bauer), which it contended disclose certain amino acid sequence homology between bacteria and cyanobacteria. The PTO argued that such homology is a further suggestion to one of ordinary skill to attempt the claimed invention. We disagree. As with the Dzelzkalns, Sekar I, Sekar II, and Ganesan references discussed above, none of these additional references disclose or suggest that cyanobacteria could serve as hosts for expression of genes encoding *Bacillus* insecticidal proteins. In fact, these

additional references suggest as much about *differences* between cyanobacteria and bacteria as they do about similarities. For example, Nierzwicki-Bauer reports that a certain nucleotide sequence (i.e., the -10 consensus sequence) in a particular cyanobacterium resembles an *E. coli* promoter, but that another nearby nucleotide sequence (the -35 region) does not. While Miller speaks of certain promoters of the bacteriophage Lambda that are recognized by both cyanobacterial and *E. coli* RNA polymerases, it also discloses that these promoters exhibited differing strengths when exposed to the different polymerases. Differing sensitivities of the respective polymerases to an inhibitor are also disclosed, suggesting differences in the structures of the initiation complexes.

The PTO asks us to agree that the prior art would lead those of ordinary skill to conclude that cyanobacteria are attractive hosts for expression of any and all heterologous genes. Again, we can not. The relevant prior art does indicate that cyanobacteria are attractive hosts for expression of both native and heterologous *genes involved in photosynthesis* (not surprisingly, for the capability of undergoing oxygenic photosynthesis is what makes the cyanobacteria unique among procaryotes). However, these references do not suggest that cyanobacteria would be equally attractive hosts for expression of *unrelated* heterologous genes, such as the claimed genes encoding *Bacillus* insecticidal proteins.

In *O'Farrell*, this court affirmed an obviousness rejection of a claim to a method for

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producing a "predetermined protein in a stable form" in a transformed bacterial host. 853 F.2d at 895, 7 USPQ2d at 1674. The cited references included a prior art publication (the Polisky reference) whose three authors included two of the three coinventor-appellants. The main difference between the prior art and the claim at issue was that in Polisky, the heterologous gene was a gene for ribosomal RNA, while the claimed invention substituted a gene coding for a predetermined protein. *Id.* at 901, 7 USPQ2d at 1679. Although, as the appellants therein pointed out, the ribosomal RNA gene is not normally translated into protein, Polisky mentioned preliminary evidence that the transcript of the ribosomal RNA gene was translated into protein, and further predicted that if a gene coding for a protein were to be substituted, extensive translation might result. *Id.* We thus affirmed, explaining that the prior art explicitly suggested the substitution that is the difference between the claimed invention and the prior art, and presented preliminary evidence suggesting that the [claimed] method could be used to make proteins.

....

... Polisky contained detailed enabling methodology for practicing the claimed invention, a suggestion to modify the prior art to practice the claimed invention, and evidence suggesting that it would be successful.

Id. at 901-02, 7 USPQ2d at 1679-80.

In contrast with the situation in *O'Farrell*, the prior art in this case offers no suggestion, explicit or implicit, of the substitution that is the difference between the claimed invention and the prior

art. Moreover, the "reasonable expectation of success" that was present in *O'Farrell* is not present here. Accordingly, we reverse the § 103 rejections.

B. Enablement

[3] The first paragraph of 35 USC 112 requires, *inter alia*, that the specification of a patent enable any person skilled in the art to which it pertains to make and use the claimed invention. Although the statute does not say so, enablement requires that the specification teach those in the art to make and use the invention without "undue experimentation." *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). That *some* experimentation may be required is not fatal; the issue is whether the amount of experimentation required is "undue." *Id.* at 736-37, 8 USPQ2d at 1404. Enablement, like obviousness, is a question of law which we independently review, although based upon underlying factual findings which we review for clear error. *See id.* at 735, 8 USPQ2d at 1402.

In response to the § 112 rejection, appellants assert that their invention is "pioneering," and that this should entitle them to claims of broad scope. Narrower claims would provide no real protection, appellants argue, because the level of skill in this art is so high, art workers could easily avoid the claims. Given the disclosure in their specification, appellants contend that any skilled microbiologist could construct vectors and transform many different cyanobacteria, using a variety of promoters and *Bacillus* DNA, and could easily determine whether or not the active *Bacillus* protein was successfully expressed by the cyanobacteria.

The PTO made no finding on whether the claimed invention is indeed "pioneering," and we need not address the issue here. With the exception of claims 47 and 48, the claims rejected under § 112 are not limited to any particular genus or species of cyanobacteria. The PTO's position is that the cyanobacteria are a diverse and relatively poorly studied group of organisms, comprising some 150 different genera, and that heterologous gene expression in cyanobacteria is "unpredictable." Appellants have not effectively disputed these assertions. Moreover, we note that only one particular species of cyanobacteria is employed in the working examples of appellants' specification, and only nine genera of cyanobacteria are mentioned in the entire document.

[4] Taking into account the relatively incomplete understanding of the biology of cyanobacteria as of appellants' filing date, as well as the limited disclosure by appellants of particular cyanobacterial genera operative in the claimed invention, we are not persuaded that the PTO erred in rejecting claims 1-46 and 50-51 under § 112, first paragraph. There is no reasonable correlation between the narrow disclosure in appellants' specification and the broad scope of protection sought in the claims encompassing gene expression in any and all cyanobacteria. *See In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (the first paragraph of § 112 requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification).

22 Accordingly, we affirm the § 112 rejection as to those claims.

In so doing we do *not* imply that patent applicants in art areas currently denominated as "unpredictable" must never be allowed generic claims encompassing more than the particular species disclosed in their specification. It is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. *In re Angstadt*, 537 F.2d 498, 502-03, 190 USPQ 214, 218 (CCPA 1976). However, there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility. Where, as here, a claimed genus represents a diverse and relatively poorly understood group of microorganisms, the required level of disclosure will be greater than, for example, the disclosure of an invention involving a "predictable" factor such as a mechanical or electrical element. *See Fisher*, 427 F.2d at 839, 166 USPQ at 24. In this case, we agree with the PTO that appellants' limited disclosure does not enable one of ordinary skill to make and use the invention as now recited in claims 1-46 and 50-51 without undue experimentation.

Remaining dependent claim 47 recites a cyanobacterium which expresses the chimeric gene of claim 1, wherein the cyanobacterium is selected from among the genera *Anacystis* and *Synechocystis*. Claim 48, which depend from claim 47, is limited to the cyanobacterium *Synechocystis* 6803. The PTO did not separately address these claims, nor indicate why they should be treated in the same manner as the claims encompassing all types of cyanobacteria. Although these claims are not limited to expression of genes encoding particular *Bacillus* proteins, we note what appears to be an extensive understanding in the prior art of the numerous *Bacillus* proteins having toxicity to various insects. The rejection of claims 47-48 under § 112 will not be sustained.

CONCLUSION

The rejection of claims 1-48 and 50-52 under 35 USC 103 is *reversed*. The rejection of claims 1-46 and 50-51 under 35 USC 112, first paragraph, is *affirmed* and the rejection of claims 47 and 48 thereunder is *reversed*.

AFFIRMED-IN-PART, REVERSED-IN-PART

Footnotes

Footnote 1. Basic vocabulary and techniques for gene cloning and expression have been described in *In re O'Farrell*, 853 F.2d 894, 895-99, 7 USPQ2d 1673, 1674-77 (Fed. Cir. 1988), and are not repeated here.

Footnote 2. All living cells can be classified into one of two broad groups, procaryotes and eucaryotes. The procaryotes comprise organisms formed of cells that do not have a distinct nucleus; their DNA floats throughout the cellular cytoplasm. In contrast, the cells of eucaryotic organisms such as man, other animals, plants, protozoa, algae and yeast have a distinct nucleus

wherein their DNA resides.

Footnote 3. "Transformed" cyanobacteria are those that have successfully taken up the foreign *Bacillus* DNA such that the DNA information has become a permanent part of the host cyanobacteria, to be replicated as new cyanobacteria are generated.

Footnote 4. "Expression" of a gene refers to the production of the protein which the gene encodes; more specifically, it is the process of transferring information from a gene (which consists of DNA) via messenger RNA to ribosomes where a specific protein is made.

Footnote 5. In the context of the claimed invention, "selectable markers" or "marker genes" refer to antibiotic-resistance conferring DNA fragments, attached to the gene being expressed, which facilitate the selection of successfully transformed cyanobacteria.

Footnote 6. *Nucleic Acids Res.* 8917 (1984).

Footnote 7. Chloramphenicol is an antibiotic; CAT is an enzyme which destroys chloramphenicol and thus imparts resistance thereto.

Footnote 8. *Biochem. and Biophys. Res. Comm.* 748 (1986).

Footnote 9. *Gene* 151 (1985).

Footnote 10. *Mol. Gen. Genet.* 181 (1983).

Footnote 11. *Mol. Gen. Genet.* 505 (1986).

Footnote 12. *J. Bacteriology* 246 (1979).

Footnote 13. RNA polymerase, the enzyme responsible for making RNA from DNA, binds at specific nucleotide sequences (promoters) in front of genes in DNA, and then moves through the gene making an RNA molecule that includes the information contained in the gene. Initiation specificity is the ability of the RNA polymerase to initiate this process specifically at a site(s) on the DNA template.

Footnote 14. *Proc. Natl. Acad. Sci. USA* 5961 (1984).

Footnote 15. *Mol. Gen. Genet.* 185 (1986).

Footnote 16. *Gene* 211 (1984).

Footnote 17. *Gene* 289 (1984).

Footnote 18. Denotes different species or organism.

Footnote 19. MPEP 706.03(n), "Correspondence of Claim and Disclosure," provides in part: In chemical cases, a claim may be so broad as to not be supported by [the] disclosure, in which case it is rejected as unwarranted by the disclosure....

Footnote 20. MPEP 796.03(z), "Undue Breadth," provides in part:

n applications directed to intentions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Sol*, 1938 C.D. 723; 497 O.G. 546. This is because in arts such as chemistry it is not obvious from the disclosure of one species, what other species will work. *In re Dreshfield*, 1940 C.D. 351; 518 O.G. 255 gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." ...

Footnote 21. *Stedman's Medical Dictionary* 1139 (24th ed. 1982) (definition of "Prokaryotae"). Prokaryotic organisms are commonly classified according to the following taxonomic hierarchy: Kingdom; Division; Class; Order; Family; Genus; Species. 3 *Bergey's Manual of Systematic Bacteriology* 1601 (1989).

Footnote 22. The enablement rejection in this case was not based upon a post-filing date state of the art, as in *In re Hogan*, 559 F.2d 595, 605-07, 194 USPQ 527, 536-38 (CCPA 1977). See also *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 USPQ2d 1461, 1464 (Fed. Cir. 1989) (citing *Hogan*); *Hormone Research Found., Inc. v. Genentech, Inc.*, 904 F.2d 1558, 1568-69, 15 USPQ2d 1039, 1047-48 (Fed. Cir. 1990) (directing district court, on remand, to consider effect of *Hogan* and *United States Steel* on the enablement analysis of *Fisher*), *cert. dismissed*, — U.S. —, 111 S. Ct. 1434 (1991). We therefore do not consider the effect of *Hogan* and its progeny on *Fisher*'s analysis of when an inventor should be allowed to "dominate the future patentable inventions of others." *Fisher*, 427 F.2d at 839, 166 USPQ at 24.

Footnote 23. The first paragraph of § 112 requires nothing more than *objective* enablement. *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is irrelevant. *Id.*

Dissenting Opinion Text

Dissent By:

Mayer, J., dissenting.

An appeal is not a second opportunity to try a case or prosecute a patent application, and we should not allow parties to "undertake to retry the entire case on appeal." *Perini America, Inc. v. Paper Converting Machine Co.*, 832 F.2d 581, 584, 4 USPQ2d 1621, 1624 (Fed. Cir. 1987); *Eaton Corp. v. Appliance Valves Corp.*, 790 F.2d 874, 877, 229 USPQ 668, 671 (Fed. Cir. 1986). But that is precisely what the court has permitted here. The PTO conducted a thorough examination of the prior art surrounding this patent application and concluded the claims would have been obvious. The board's decision based on the examiner's answer which comprehensively explains the rejection is persuasive and shows how the evidence supports the legal conclusion that the claims would have been obvious. Yet, the court ignores all this and conducts its own examination, if you will, as though the examiner and board did not exist. Even if thought this opinion were more persuasive than the board's, I could not join it because it misperceives the role of the court.

The scope and content of the prior art, the similarity between the prior art and the claims, the level of ordinary skill in the art, and what the prior art teaches are all questions of fact. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966); *Jurgens v. McKasy*, 927 F.2d 1552, 1560, 18 USPQ2d 1031, 1037 (Fed. Cir. 1991). And "[w]here there are two permissible views of

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the evidence, the factfinder's choice between them cannot be clearly erroneous." *Anderson v. City of Bessemer City*, 470 U.S. 564, 574 (1985). The mere denomination of obviousness as a question of law does not give the court license to decide the factual matters afresh and ignore the requirement that they be respected unless clearly erroneous. *In re Woodruff*, 919 F.2d 1575, 1577, 16 USPQ2d 1934, 1935 (Fed. Cir. 1990); *In re Kulling*, 897 F.2d 1147, 1149, 14 USPQ2d 1056, 1057 (Fed. Cir. 1990). There may be more than one way to look at the prior art, but on this record we are bound by the PTO's interpretation of the evidence because it is not clearly erroneous and its conclusion is unassailable. I would affirm on that basis.

- End of Case -

In re Lee, 61 USPQ2d 1430 (CA FC 2002)

61 USPQ2D 1430

In re Lee

U.S. Court of Appeals Federal Circuit

No. 00-1158

Decided January 18, 2002

Headnotes

PATENTS

[1] Practice and procedure in Patent and Trademark Office — Board of Patent Appeals and Interferences — In general (§110.1101)

Patentability/Validity — Obviousness — Combining references (§115.0905)

Patentability/Validity — Obviousness — Evidence of (§115.0906)

Rejection of patent application for obviousness under 35 U.S.C. §103 must be based on evidence comprehended by language of that section, and search for and analysis of prior art includes evidence relevant to finding of whether there is teaching, motivation, or suggestion to select and combine references relied on as evidence of obviousness; factual inquiry whether to combine references must be thorough and searching, based on objective evidence of record, and Board of Patent Appeals and Interferences must explain reasons why one of ordinary skill in art would have been motivated to select references and to combine them to render claimed invention obvious.

[2] Patentability/Validity — Obviousness — Combining references (§115.0905)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Judicial review — Standard of review —Patents (§410.4607.09)

Board of Patent Appeals and Interferences improperly relied upon “common knowledge and common sense” of person of ordinary skill in art to find invention of patent application obvious over combination of two prior art references, since factual question of motivation to select and combine references is material to patentability, and could not be resolved on subjective belief and unknown authority, since deferential review of agency decisions under Administrative Procedure Act reinforces obligation of board to develop evidentiary basis for its findings, since board's rejection of need for any specific hint or suggestion in particular reference to support combination constituted omission of relevant factor required by precedent, and thus was both legal error and arbitrary agency action, since board's findings must extend to all material facts and be documented on record, and since “common knowledge and common sense” are not specialized knowledge and expertise of agency contemplated by APA, and may not be substituted for evidence, although they may be applied to analysis of evidence.

PATENTS

[3] Practice and procedure in Patent and Trademark Office —Board of Patent Appeals and Interferences — In general (§110.1101)

Patentability/Validity — Obviousness — Evidence of (§115.0906)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Judicial review — Standard of review —Patents (§410.4607.09)

Patent examiners and Board of Patent Appeals and Interferences, in relying on what they assert to be general knowledge to negate patentability on ground of obviousness, must articulate that knowledge and place it on record, since examiners and board are presumed

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to act from viewpoint of person of ordinary skill in art in finding relevant facts, assessing significance of prior art, and making ultimate determination of obviousness issue; failure to do so is not consistent with either effective administrative procedure or effective judicial review, and

board cannot rely on conclusory statements when dealing with particular combinations of prior art and specific claims, but must set forth rationale on which it relies.

[4] Procedure — Court of Appeals for the Federal Circuit (§410.03)

Procedure — Judicial review — Standard of review —Patents (§410.4607.09)

U.S. Court of Appeals for the Federal Circuit will not consider proposed alternative grounds for affirming decision of Board of Patent Appeals and Interferences rejecting patent application for obviousness, since alternative grounds were made at oral argument and constitute post hoc rationalization for agency action, consideration of which would deprive aggrieved party of fair opportunity to support its position.

Case History and Disposition

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Patent application of Sang-Su Lee, serial no. 07/631,210, directed to method of automatically displaying functions of video display device and demonstrating how to select and adjust functions to facilitate user response. Applicant appeals from decision upholding rejection of all claims for obviousness, and from reaffirmation of that decision on reconsideration. Reversed and remanded.

Attorneys:

Richard H. Stern and Robert E. Bushnell, Washington, D.C., for Sang Su Lee.

Sidney O. Johnson Jr., associate solicitor, John M. Whealan, solicitor, and Raymond T. Chen, Maximilian R. Peterson, and Mark Nagumo, associate solicitors, Arlington, Va., for Director of U.S. Patent and Trademark Office.

Judge:

Before Newman, Clevenger, and Dyk, circuit judges.

Opinion Text

Opinion By:

Newman, J.

Sang-Su Lee appeals the decision of the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office, rejecting all of the claims of Lee's patent application Serial No. 07/631,210 entitled "Self-Diagnosis and Sequential-Display Method of Every

Function.” We vacate the Board's decision for failure to meet the adjudicative standards for review under the Administrative Procedure Act, and remand for further proceedings.

The Prosecution Record

Mr. Lee's patent application is directed to a method of automatically displaying the functions of a video display device and demonstrating how to select and adjust the functions in order to facilitate response by the user. The display and demonstration are achieved using computer-managed electronics, including pulse-width modulation and auto-fine-tuning pulses, in accordance with procedures described in the specification. Claim 10 is representative:

10. A method for automatically displaying functions of a video display device, comprising:
determining if a demonstration mode is selected;
if said demonstration mode is selected, automatically entering a picture adjustment mode having a picture menu screen displaying a list of a plurality of picture functions; and
automatically demonstrating selection and adjustment of individual ones of said plurality of picture functions. The examiner rejected the claims on the ground of obviousness, citing the combination of two references: United States Patent No. 4,626,892 to Nortrup, and the Thunderchopper Helicopter Operations Handbook for a video game. The Nortrup reference describes a television set having a menu display by which the user can adjust various picture and audio functions; however, the Nortrup display does not include a demonstration of how to adjust the functions. The Thunderchopper Handbook describes the Thunderchopper game's video display as having a “demonstration mode” showing how to play the game; however, the Thunderchopper Handbook makes no mention of the adjustment of picture or audio functions. The examiner held that it

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would have been obvious to a person of ordinary skill to combine the teachings of these references to produce the Lee system.

Lee appealed to the Board, arguing that the Thunderchopper Handbook simply explained how to play the Thunderchopper game, and that the prior art provided no teaching or motivation or suggestion to combine this reference with Nortrup, or that such combination would produce the Lee invention. The Board held that it was not necessary to present a source of a teaching, suggestion, or motivation to combine these references or their teachings. The Board stated:

The conclusion of obviousness may be made from common knowledge and common sense of a person of ordinary skill in the art without any specific hint or suggestion in a particular reference. Board op. at 7. The Board did not explain the “common knowledge and common sense” on which it relied for its conclusion that “the combined teachings of Nortrup and Thunderchopper would have suggested the claimed invention to those of ordinary skill in the art.”

Lee filed a request for reconsideration, to which the Board responded after five years. The

Board reaffirmed its decision, stating that the Thunderchopper Handbook was “analogous art” because it was “from the same field of endeavor” as the Lee invention, and that the field of video games was “reasonably pertinent” to the problem of adjusting display functions because the Thunderchopper Handbook showed video demonstrations of the “features” of the game. On the matter of motivation to combine the Nortrup and Thunderchopper references, the Board stated that “we maintain the position that we stated in our prior decision” and that the Examiner's Answer provided “a well reasoned discussion of why there is sufficient motivation to combine the references.” The Board did not state the examiner's reasoning, and review of the Examiner's Answer reveals that the examiner merely stated that both the Nortrup function menu and the Thunderchopper demonstration mode are program features and that the Thunderchopper mode “is user-friendly” and it functions as a tutorial, and that it would have been obvious to combine them.

Lee had pressed the examiner during prosecution for some teaching, suggestion, or motivation in the prior art to select and combine the references that were relied on to show obviousness. The Examiner's Answer before the Board, plus a Supplemental Answer, stated that the combination of Thunderchopper with Nortrup “would have been obvious to one of ordinary skill in the art since the demonstration mode is just a programmable feature which can be used in many different device[s] for providing automatic introduction by adding the proper programming software,” and that “another motivation would be that the automatic demonstration mode is user friendly and it functions as a tutorial.” The Board adopted the examiner's answer, stating “the examiner has provided a well reasoned discussion of these references and how the combination of these references meets the claim limitations.” However, perhaps recognizing that the examiner had provided insufficient justification to support combining the Nortrup and Thunderchopper references, the Board held, as stated *supra*, that a “specific hint or suggestion” of motivation to combine was not required.

This appeal followed.

Judicial Review

Tribunals of the PTO are governed by the Administrative Procedure Act, and their rulings receive the same judicial deference as do tribunals of other administrative agencies. *Dickinson v. Zurko*, 527 U.S. 150, 50 USPQ2d 1930 (1999). Thus on appeal we review a PTO Board's findings and conclusions in accordance with the following criteria:

5 U.S.C. §706(2) The reviewing court shall—

(2) hold unlawful and set aside agency actions, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

* * * *

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute;

For judicial review to be meaningfully achieved within these strictures, the agency tribunal

must present a full and reasoned explanation of its decision. The agency tribunal

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must set forth its findings and the grounds thereof, as supported by the agency record, and explain its application of the law to the found facts. The Court has often explained:

The Administrative Procedure Act, which governs the proceedings of administrative agencies and related judicial review, establishes a scheme of "reasoned decisionmaking." Not only must an agency's decreed result be within the scope of its lawful authority, but the process by which it reaches that result must be logical and rational. *Allentown Mack Sales and Service, Inc. v. National Labor Relations Bd.*, 522 U.S. 359, 374 (1998) (citation omitted). This standard requires that the agency not only have reached a sound decision, but have articulated the reasons for that decision. The reviewing court is thus enabled to perform meaningful review within the strictures of the APA, for the court will have a basis on which to determine "whether the decision was based on the relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971). Judicial review of a Board decision denying an application for patent is thus founded on the obligation of the agency to make the necessary findings and to provide an administrative record showing the evidence on which the findings are based, accompanied by the agency's reasoning in reaching its conclusions. *See In re Zurko*, 258 F.3d 1379, 1386, 59 USPQ2d 1693, 1697(Fed. Cir. 2001) (review is on the administrative record); *In re Gartside*, 203 F.3d 1305, 1314, 53 USPQ2d 1769, 1774(Fed. Cir. 2000) (Board decision "must be justified within the four corners of the record").

[1] As applied to the determination of patentability *vel non* when the issue is obviousness, "it is fundamental that rejections under 35 U.S.C. §103 must be based on evidence comprehended by the language of that section." *In re Grasselli*, 713 F.2d 731, 739, 218 USPQ 769, 775(Fed. Cir. 1983). The essential factual evidence on the issue of obviousness is set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966) and extensive ensuing precedent. The patent examination process centers on prior art and the analysis thereof. When patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness. *See, e.g., McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351-52, 60 USPQ2d 1001, 1008(Fed. Cir. 2001) ("the central question is whether there is reason to combine [the] references," a question of fact drawing on the *Graham* factors).

"The factual inquiry whether to combine references must be thorough and searching." *Id.* It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with. *See, e.g., Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1124-25, 56 USPQ2d 1456, 1459 (Fed. Cir. 2000) ("a showing of a

suggestion, teaching, or motivation to combine the prior art references is an "essential component of an obviousness holding") (quoting *C.R. Bard, Inc., v. M3 Systems, Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232(Fed. Cir. 1998)); *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617(Fed. Cir. 1999) ("Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references."); *In re Dance*, 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637(Fed. Cir. 1998) (there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant); *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600(Fed. Cir. 1988) ("teachings of references can be combined *only* if there is some suggestion or incentive to do so.") (emphasis in original) (quoting *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933(Fed. Cir. 1984)).

The need for specificity pervades this authority. *See, e.g., In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317(Fed. Cir. 2000) ("particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed"); *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459(Fed. Cir. 1998) ("even when the level of skill in the art is high, the Board must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination.

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In other words, the Board must explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious."); *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783(Fed. Cir. 1992) (the examiner can satisfy the burden of showing obviousness of the combination "only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references").

[2] With respect to Lee's application, neither the examiner nor the Board adequately supported the selection and combination of the Nortrup and Thunderchopper references to render obvious that which Lee described. The examiner's conclusory statements that "the demonstration mode is just a programmable feature which can be used in many different device[s] for providing automatic introduction by adding the proper programming software" and that "another motivation would be that the automatic demonstration mode is user friendly and it functions as a tutorial" do not adequately address the issue of motivation to combine. This factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority. It is improper, in determining whether a person of ordinary skill would have been led to this combination of references, simply to "[use] that which the inventor taught against

its teacher.” *W.L. Gore v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983). Thus the Board must not only assure that the requisite findings are made, based on evidence of record, but must also explain the reasoning by which the findings are deemed to support the agency's conclusion.

Deferential judicial review under the Administrative Procedure Act does not relieve the agency of its obligation to develop an evidentiary basis for its findings. To the contrary, the Administrative Procedure Act reinforces this obligation. *See, e.g., Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Ins. Co.*, 463 U.S. 29, 43 (1983) (“the agency must examine the relevant data and articulate a satisfactory explanation for its action including a ‘rational connection between the facts found and the choice made.’”) (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)); *Securities & Exchange Comm'n v. Chenery Corp.*, 318 U.S. 80, 94 (1943) (“The orderly function of the process of review requires that the grounds upon which the administrative agency acted are clearly disclosed and adequately sustained.”).

In its decision on Lee's patent application, the Board rejected the need for “any specific hint or suggestion in a particular reference” to support the combination of the Nortrup and Thunderchopper references. Omission of a relevant factor required by precedent is both legal error and arbitrary agency action. *See Motor Vehicle Manufacturers*, 463 U.S. at 43 (“an agency rule would be arbitrary and capricious if the agency ... entirely failed to consider an important aspect of the problem”); *Mullins v. Department of Energy*, 50 F.3d 990, 992 (Fed. Cir. 1995) (“It is well established that agencies have a duty to provide reviewing courts with a sufficient explanation for their decisions so that those decisions may be judged against the relevant statutory standards, and that failure to provide such an explanation is grounds for striking down the action.”). As discussed in *National Labor Relations Bd. v. Ashkenazy Property Mgt. Corp.*, 817 F.2d 74, 75 (9th Cir. 1987), an agency is “not free to refuse to follow circuit precedent.”

The foundation of the principle of judicial deference to the rulings of agency tribunals is that the tribunal has specialized knowledge and expertise, such that when reasoned findings are made, a reviewing court may confidently defer to the agency's application of its knowledge in its area of expertise. Reasoned findings are critical to the performance of agency functions and judicial reliance on agency competence. *See Baltimore and Ohio R. R. Co. v. Aberdeen & Rockfish R. R. Co.*, 393 U.S. 87, 91-92 (1968) (absent reasoned findings based on substantial evidence effective review would become lost “in the haze of so-called expertise”). The “common knowledge and common sense” on which the Board relied in rejecting Lee's application are not the specialized knowledge and expertise contemplated by the Administrative Procedure Act. Conclusory statements such as those here provided do not fulfill the agency's obligation. This court explained in *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697, that “deficiencies of the cited references cannot be remedied by

the Board's general conclusions about what is 'basic knowledge' or 'common sense.'" The Board's findings must extend to all material facts and must be documented on the record, lest the "haze of so-called expertise" acquire insulation from accountability. "Common knowledge and common sense," even if assumed to derive from the agency's expertise, do not substitute for authority when the law requires authority. *See Allentown Mack*, 522 U.S. at 376 ("Because reasoned decisionmaking demands it, and because the systemic consequences of any other approach are unacceptable, the Board must be required to apply in fact the clearly understood legal standards that it enunciates in principle")

The case on which the Board relies for its departure from precedent, *In re Bozek*, 416 F.2d 1385, 163 USPQ 545 (CCPA 1969), indeed mentions "common knowledge and common sense," the CCPA stating that the phrase was used by the Solicitor to support the Board's conclusion of obviousness based on evidence in the prior art. *Bozek* did not hold that common knowledge and common sense are a substitute for evidence, but only that they may be applied to analysis of the evidence. *Bozek* did not hold that objective analysis, proper authority, and reasoned findings can be omitted from Board decisions. Nor does *Bozek*, after thirty-two years of isolation, outweigh the dozens of rulings of the Federal Circuit and the Court of Customs and Patent Appeals that determination of patentability must be based on evidence. This court has remarked, in *Smiths Industries Medical Systems, Inc. v. Vital Signs, Inc.*, 183 F.3d 1347, 1356, 51 USPQ2d 1415, 1421 (Fed. Cir. 1999), that *Bozek's* reference to common knowledge "does not in and of itself make it so" absent evidence of such knowledge.

[3] The determination of patentability on the ground of unobviousness is ultimately one of judgment. In furtherance of the judgmental process, the patent examination procedure serves both to find, and to place on the official record, that which has been considered with respect to patentability. The patent examiner and the Board are deemed to have experience in the field of the invention; however, this experience, insofar as applied to the determination of patentability, must be applied from the viewpoint of "the person having ordinary skill in the art to which said subject matter pertains," the words of section 103. In finding the relevant facts, in assessing the significance of the prior art, and in making the ultimate determination of the issue of obviousness, the examiner and the Board are presumed to act from this viewpoint. Thus when they rely on what they assert to be general knowledge to negate patentability, that knowledge must be articulated and placed on the record. The failure to do so is not consistent with either effective administrative procedure or effective judicial review. The board cannot rely on conclusory statements when dealing with particular combinations of prior art and specific claims, but must set forth the rationale on which it relies.

Alternative Grounds

[4] At oral argument the PTO Solicitor proposed alternative grounds on which this court might

affirm the Board's decision. However, as stated in *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962), "courts may not accept appellate counsel's *post hoc* rationalization for agency action." Consideration by the appellate tribunal of new agency justifications deprives the aggrieved party of a fair opportunity to support its position; thus review of an administrative decision must be made on the grounds relied on by the agency. "If those grounds are inadequate or improper, the court is powerless to affirm the administrative action by substituting what it considers to be a more adequate or proper basis." *Securities & Exchange Comm'n v. Chenery Corp.*, 332 U.S. 194, 196 (1947). As reiterated in *Federal Election Comm'n v. Akins*, 524 U.S. 11, 25 (1998), "If a reviewing court agrees that the agency misinterpreted the law, it will set aside the agency's action and remand the case — even though the agency (like a new jury after a mistrial) might later, in the exercise of its lawful discretion, reach the same result for a different reason." Thus we decline to consider alternative grounds that might support the Board's decision.

Further Proceedings

Sound administrative procedure requires that the agency apply the law in accordance with statute and precedent. The agency tribunal must make findings of relevant facts, and present its reasoning in sufficient detail that the court may conduct meaningful review of the agency action. In *Radio-Television News Directors Ass'n v. FCC*, 184 F.3d 872 (D.C.

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Cir. 1999) the court discussed the "fine line between agency reasoning that is 'so crippled as to be unlawful' and action that is potentially lawful but insufficiently or inappropriately explained," quoting from *Checkosky v. Securities & Exch. Comm'n*, 23 F.3d 452, 464 (D.C. Cir. 1994); the court explained that "[i]n the former circumstance, the court's practice is to vacate the agency's order, while in the latter the court frequently remands for further explanation (including discussion of the relevant factors and precedents) while withholding judgment on the lawfulness of the agency's proposed action." *Id.* at 888. In this case the Board's analysis of the Lee invention does not comport with either the legal requirements for determination of obviousness or with the requirements of the Administrative Procedure Act that the agency tribunal set forth the findings and explanations needed for "reasoned decisionmaking." Remand for these purposes is required. See *Overton Park*, 401 U.S. at 420-221 (remanding for further proceedings appropriate to the administrative process).

VACATED AND REMANDED

Footnotes

1 *Ex parte Lee*, No. 1994-1989 (Bd. Pat. App. & Int. Aug. 30, 1994; on reconsideration Sept. 29, 1999).

**- End of Case -
A0A5D6V4M8**

In re ROYKA AND MARTIN, 180 USPQ 580 (CCPA 1974)

In re ROYKA AND MARTIN

**(CCPA)
180 USPQ 580**

Decided Feb. 7, 1974

No. 9092

U.S. Court of Customs and Patent Appeals

Headnotes

PATENTS

1. Patentability — Anticipation — Combining references (§ 51.205)

To support anticipation rejection, all elements of claim must be found in reference.

2. Construction of specification and claims — Broad or narrow — In general (§ 22.101)

Construction of specification and claims — By specification and drawings — In general (§ 22.251)

Claims are not read in a vacuum; while they are given broadest reasonable interpretation during prosecution, their terms still must be given meaning called for by specification of which they form a part.

3. Patentability — Anticipation — In general (§ 51.201)

Anticipation requires a finding that claimed invention be disclosed; it is not enough to say that applicants' invention and the reference are both usable for instruction and both consist of permanent and removable printings on paper.

4. Patentability — Subject matter for patent monopoly — Printed matter (§ 51.611)

It is not a valid reason for rejection that claim is merely a printed matter variation of design of reference; printed matter may very well constitute structural limitations upon which patentability can be predicated.

Particular patents—Answer System

Royka and Martin, Responsive Answer System, claims 28 and 30 to 36 of application allowed.

Case History and Disposition:

Appeal from Board of Appeals of the Patent Office.

Application for patent of Stephen F. Royka and Robert G. Martin, Serial No. 648,701, filed June 26, 1967; Patent Office Group 336. From decision rejecting claims 28 and 30 to 36, applicants appeal. Reversed.

Attorneys:

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JOSEPH F. NAKAMURA (FRED W. SHERLING of counsel) for Commissioner of Patents.

Judge:

Before MARKEY, Chief Judge, and RICH, BALDWIN, LANE, and MILLER, Associate Judges.

Opinion Text

Opinion By:

RICH, Judge.

This appeal is from the decision of the Patent Office Board of Appeals affirming the examiner's rejection of claims 28 and 30-36 of application serial No. 648,701, filed June 26, 1967, entitled "Responsive Answer System." We reverse.

The Invention

The appealed claims are directed to a device in the nature of an answer sheet for use in self-instruction and testing. The answer sheet may be associated with questions or separate therefrom. The essential features of the invention are that there are printed on the answer sheet in "response areas" meaningful information in permanent printing and confusing information in printing which can be removed, as by an eraser, both being legible so that a student, seeing a choice of answers to a question, must make a selection. Having made a selection, he then applies an eraser to the selected response area and some of the information will be readily removed. What remains advises him of the correctness or otherwise of his answer. The following figures from the drawings are illustrative:

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Fig. 1A shows two response areas to a given question before any removing action by the student has taken place and Fig. 1B shows the permanent information remaining in each after erasure of the removable information. Of course, if the student makes an initial choice of area A, showing up "YES" or some other indication of a correct answer, he will not need to proceed further and erase the B area. In a modified form of the invention, a wrong selection, plus erasure, may expose, instead of or in addition to a statement that the answer is wrong, a number or other reference to further material which is to be studied.

A preferred method of printing the permanent meaningful information and the removable confusing information is by that type of xerography in which a fusible toner is used, the permanence of the printing depending on the extent to which the toner image is "fixed" or fused by heat. By successive printings of the two kinds of information with fixing to different degrees, one image can be made permanent and the other made subject to easy removal, both images retaining such similarity of appearance that the user of the answer sheet cannot tell them apart.

Claim 28 is the principal claim, all others being dependent thereon, and reads as follows:

- 28. A device for selectively indicating information comprising
 - a support having response areas for presenting information for selection,
 - permanent printing indicative of meaningful information permanently fixed to said support within a response area, and
 - removable printing indicative of confusing information removably fixed to said

support within a response area,

said meaningful and confusing information being substantially legible even when said permanent and removable printing are fixed over one another on said support,

said permanent and removable printing being substantially similar such that an observer cannot determine which information is permanent and which is removable

whereby the information within a response area is selected by attempting to remove the printing therein with the failure to remove printing identifying meaningful information.

Claims 30-36 add limitations which need not be considered except for noting that claims 33 and 34 alone specify the use of a xerographic toner, for which reason they were rejected on a different ground from the other claims.

The Rejection

The following references were relied on:

Reid et al. (Reid) 356,695 Jan. 25, 1887

Bernstein et al. (Bernstein) 3,055,117 Sep. 25, 1962

Lein et al. (Lein) 3,364,857 Jan. 23, 1968 (filed Feb. 2, 1966)

Claims 28, 30, 31, and 32 were rejected as anticipated under 35 U.S.C. 102 by Bernstein; claims 28, 31, 32, 35, and 36 were rejected as anticipated under § 102 by Reid; and claims 33 and 34 were rejected under 35 U.S.C. 103 for obviousness, on either Bernstein or Reid in view of Lein. These were the examiner's rejections and the board affirmed them, adhering to its decision on reconsideration.

Bernstein discloses an answer sheet in which printed information representing a response is "temporarily concealed from the observer" and he discloses a number of different ways of effectively concealing the response. His specification states:

The objects of the invention are accomplished by utilizing the hiding media to confuse the participant and to render the response and the hiding media indistinguishable and thus conceal the presence, absence, nature or position of the response from the participant. This may be effectuated by careful attention being paid to a number of factors including the design, color and position of the hiding or confusing media.

Fig. 1 of Bernstein's drawings illustrates some of his concealing means:

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The following is the written description:

Referring now to the drawing, FIG. 1 illustrates some of the many optically confusing patterns which may be positioned between the printed structure to be concealed and the point of observation. Column 11 shows the information which is to be concealed. This information is repeated in columns 12 through 16 but in each case is concealed by a pattern in accordance with the present invention. Column 12 utilizes a pattern comprising an alphabetical maze in both line and half tone screen. Column 13 utilizes a pattern comprising an absorbing field having a plurality of irregular dot-like interstices. Column 14 utilizes a pattern comprising a maze of plus signs combined with dots. Columns 15 and 16 illustrate irregular and non-repetitious patterns.

Bernstein says that if at least 50% of the response is actually covered by the opaque portions of the confusion pattern, complete concealment is obtained. He also says that added means of concealment may be used, such as scoring and embossing and perforating the paper in order to scatter the light or let it shine through.

Reid is entitled "Transformation Picture and Print." The invention is said to be useful for advertisements, Christmas cards, birthday cards, valentines, and the like and as a source of amusement and instruction for children. It consists of a picture or print, part of which is permanently printed and part of which is removable from the paper on which it is printed. For the latter various soluble undercoatings or inks are described. If the picture is washed with a solvent, which may be water, the removable part disappears and the pictorial and/or typographic matter changes. The invention is illustrated by a typical nineteenth century temperance propaganda piece depicting the evils of drink. In the finished picture there are three scenes from left to right: Scene 1, the innocent child leads her father home from the pub; Scene 2, Father sits slumped in the kitchen chair with his bottle beside him, the family wash hanging above his head, this picture being entitled "The Effects of Drink"; Scene 3, Mother stands in front of a sign reading "Pawn Shop." Across the bottom of the picture is a legend which says "Wash the above and see what water will do." Fig. II shows the result of washing with water: Scene 1, a handsome young man and his happy daughter stroll on the street; Scene 2, Father sits erect in a well-appointed room at a cloth-covered table, apparently having a cup of tea, obviously a gentleman; Scene 3, Mother beams from the sideline and the Pawn Shop sign has vanished. Two new subscriptions appear and the words "The" and "Drink" have disappeared, the resultant being a new picture title reading "The Beneficial Effects of Temperance." "The Beneficial" and "Temperance" were covered by some soluble opaque in the original picture. No doubt the overall effect is instruction. Perhaps there was amusement in bringing about the transformation.

Lein relates to xerography and is relied on only for its disclosure of the removability of partially fused toner and the permanence of fully fused toner.

Opinion

[1] As to the § 102 anticipation rejections, it will suffice to consider independent claim 28. If it is not fully met by Reid or Bernstein, neither are the more limited dependent claims. It is elementary that to support an anticipation rejection, all elements of the claim must be found in the reference. We do not find claim 28 anticipated by Bernstein because, as we read the claim, it requires the display of *legible* meaningful and *legible* confusing *information* simultaneously, between which the user of the device may make a selection before he undertakes to remove any of the information from the response area selected by him. The element we find most clearly missing, contrary to the reasoning of the examiner and the board, is the legible confusing *information*. The Patent Office proposes to read this limitation on Bernstein's confusion patterns which are nothing but meaningless obscuring screens, conveying no information and providing the user with no basis for making a *selection*, as called for by claim 28. In appellants' device the legible confusing information—i.e., the wrong answers—are legible in the sense that they can be read as intelligible words, not merely a jumble of type serving to obscure the words of the wrong answers.

Appellants were fully aware of Bernstein and discussed its disclosures in their specification, distinguishing from this and other prior art, saying, in part:

The inventive concept hereof confuses not by physical blocking as taught by the prior art, but by compounding, associating (including disarranging) permanent information with confusing information, usually at least some of which is similar in character to the permanent information as to render it impossible to tell which is permanent and which is removable confusing information. In the invention, generally no attempt is made to designedly physically cover the permanent information, but to confuse it beyond interpretation by the presentation of extraneous, removable, confusing information.

[2] Claims are not to be read in a vacuum and while it is true they are to be given the broadest *reasonable* interpretation during

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prosecution, their terms still have to be given the meaning called for by the specification of which they form a part. We cannot read the terms "legible" and "information" on Bernstein's confusion patterns, as did the examiner and the board. They are not "legible," as appellants use the term, and they convey no information.

As to anticipation by Reid, we find neither appellants' basic concept nor the substance of claim 28 to be disclosed. Apparently the solicitor could find little to support the rejection in Reid for all he says in his brief—so far as claim 28 is concerned—is:

Reid discloses a sheet which may be used for instruction and which may have a removable design partly covering a fixed design * * *. Therefore, the disclosure of the reference encompasses the arrangement wherein a removable design covers a fixed design

with both designs being substantially legible.

[3] But claim 28 does not call for an arrangement wherein a removable design covers a fixed design. It calls for response areas, which Reid does not have, containing meaningful information in permanent printing together with removable printing conveying confusing information, both legible at the same time, between which a "selection" can be made. The only choice offered to the user by Reid is to follow the instruction to wash the whole visible picture with water or other solvent, thus removing the overprinting, to discover what the permanent picture is. The Patent Office attempt to read claim 28 on this reference is a tour de force. We hold that Reid does not anticipate for failure to meet the limitations of claim 28 to "response areas," to the presentation of two categories of information (meaningful-permanent and removable-confusing) within such areas, and the possibility of selection. Anticipation requires a finding that the claimed invention be disclosed. It is not enough to say that appellants' invention and the reference are both usable for instruction and both consist of permanent and removable printings on paper, as did the solicitor.

The dependent claims rejected with claim 28, as anticipated under § 102, are not anticipated since claim 28 is not anticipated. Some of them merely add features which are disclosed by the references and some do not. Insofar as they do not, they further negative anticipation. The examiner recognized this fact as to claims 33 and 34, which are limited to xerography, and therefore did not reject them under § 102. Similarly, he did not reject claim 30 on Reid or claims 35 and 36 on Bernstein. We find that claims 35 and 36 contain limitations which additionally distinguish from Reid. We have already noted that Reid has no "response areas" as required by claim 28 and so Reid does not disclose the structure of claim 35 which additionally requires both the correct and incorrect answers to appear within the same response area.

[4] As to claim 36, the examiner said it "is merely a printed matter variation of the design of the reference," Reid. This is not a valid reason for rejection. Printed matter may very well constitute structural limitations upon which patentability can be predicated. We have commented on this matter in *In re Jones*, 54 CCPA 1218, 373 F.2d 1007, 153 USPQ 77 (1967); and *In re Miller*, 57 CCPA 809, 418 F.2d 1392, 164 USPQ 46 (1969), and will not repeat ourselves. The limitations of claim 36 are not remotely suggested by Reid.

There remains the § 103 rejection of claims 33 and 34. Do they, taken together with all of the limitations of claim 28 from which they depend, define obvious subject matter? The difference between claim 28 and these two dependent claims is that they add the limitations to xerography. If Bernstein and Reid showed the claimed invention except for xerography, the addition of the Lein reference would make the subject matter of the claims obvious. But that is not the situation here. Adding the knowledge of xerographic technology to Bernstein or Reid still does not make the invention of claims 33 and 34 obvious for the same reasons we have given above in discussing anticipation. The essence of appellants' invention, as set forth in claim 28, is still missing notwithstanding the addition of the Lein reference and we see nothing in the combinations of references which would have made the invention obvious to one of ordinary

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skill in the art at the time it was made. We will, therefore, reverse this rejection.

The decision of the board is *reversed*.

- End of Case -